

① Form PTO-1449 (modified)

Atty. Docket No.  
CLFR:010US/TMBSerial No.  
10/010,081

## List of Patents and Publications for Applicant's

## INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Applicant  
Didier Trono  
Patrick SalmonFiling Date:  
November 9, 2001Group:  
Unknown 1636U.S. Patent Documents  
See Page 1Foreign Patent Documents  
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## U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
2	A1	5,686,279	11/11/97	Finer <i>et al.</i>	435	172.3	6/10/94
2	A2	5,994,136	11/30/99	Naldini <i>et al.</i>	435	455	12/12/97
2	A3	6,013,516	1/11/00	Verma <i>et al.</i>	435	325	10/6/95
2	A4	6,017,758	1/25/00	Haselton, III <i>et al.</i>	435	325	2/20/98
2	A5	6,084,063	7/4/00	Vonakis <i>et al.</i>	530	324	2/6/98
2	A6	6,136,597	10/24/00	Hope <i>et al.</i>	435	325	9/18/97
2	A7	6,165,782	12/26/00	Naldini <i>et al.</i>	435	320.1	3/18/99
2	A8	6,207,455 B1	3/27/01	Chang	435	457	9/22/97
2	A9	6,218,181 B1	4/17/01	Verma <i>et al.</i>	435	369	9/3/98
2	A10	6,218,186 B1	4/17/01	Choi <i>et al.</i>	435	456	4/17/01
2	A11	6,242,258 B1	6/5/01	Haselton, III <i>et al.</i>	435	455	1/5/00
2	A12	6,271,359 B1	8/7/01	Norris <i>et al.</i>	536	23.1	4/14/99
2	A13	6,277,633 B1	8/21/01	Olsen	435	320.1	5/12/98

## Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
2	C1	Akkina <i>et al.</i> , "High-efficiency gene transfer into CD34+ cells with a human immunodeficiency virus type I-based retroviral vector pseudotyped with vesicular stomatitis virus envelope glycoprotein G," <i>J. Virol.</i> , 70:2581-2585, 1996.

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Exam. Init.	Ref. Des.	Citation
Sc	C2	An <i>et al.</i> , "Marking and gene expression by a lentivirus vector in transplanted human and nonhuman primate CD34(+) cells," <i>J. Virol.</i> , 74:1286-1295, 2000.
Sc	C3	Arrighi <i>et al.</i> , "Long-term culture of human CD34(+) progenitors with FLT3-ligand, thrombopoietin, and stem cell factor induces extensive amplification of a CD34(-)CD14(-) and CD34(-)CD14(+) dendritic cell precursor," <i>Blood</i> , 93:2244-2252, 1999.
Sc	C4	Berkhout <i>et al.</i> , "Tat Trans-activates the Human Immunodeficiency Virus Through a Nascent RNA Target," <i>Cell</i> , 59:273-282, 1989.
Sc	C5	Bhatia <i>et al.</i> , "Quantitative analysis reveals expansion of human hematopoietic repopulating cells after short-term <i>ex vivo</i> culture," <i>J. Exp. Med.</i> , 186:619-624, 1997.
Sc	C6	Blömer <i>et al.</i> , "Highly efficient and sustained gene transfer in adult neurons with a lentivirus vector," <i>J. Virol.</i> , 71:6641-6649, 1997.
Sc	C7	Brown <i>et al.</i> , "Efficient polyadenylation within the human immunodeficiency virus type 1 long terminal repeat requires flanking U3-specific sequences," <i>J. Virol.</i> , 65:3340-3343, 1991.
Sc	C8	Carbonelli <i>et al.</i> , "A plasmid vector for isolation of strong promoters in <i>E. coli</i> ," <i>FEMS Microbiol Lett.</i> 177(1):75-82, 1999.
Sc	C9	Case <i>et al.</i> , "Stable transduction of quiescent CD34(+)CD38(-) human hematopoietic cells by HIV-1 based lentiviral vectors," <i>Proc. Natl. Acad. Sci. USA</i> , 96:2988-2993, 1999.
Sc	C10	Chandler <i>et al.</i> , "RNA splicing specificity determined by the coordinated action of RNA recognition motifs in SR proteins," <i>Proc Natl Acad Sci U S A.</i> 94(8):3596-3601, 1997.
Sc	C11	Cherrington and Ganem, "Regulation of polyadenylation in human immunodeficiency virus (HIV): contributions of promoter proximity and upstream sequences," <i>Embo. J.</i> , 11:1513-1524, 1992.
Sc	C12	Cocea, "Duplication of a region in the multiple cloning site of a plasmid vector to enhance cloning-mediated addition of restriction sites to a DNA fragment," <i>Biotechniques</i> , 23:814-816, 1997
Sc	C13	Corbeau, <i>et al.</i> , "Efficient gene transfer by a human immunodeficiency virus type 1 (HIV-1)-derived vector utilizing a stable HIV packaging cell line," <i>PNAS U.S.A.</i> , 93(24):14070-14075, 1996.

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Exam. Init.	Ref. Des.	Citation
<i>Sc</i>	C14	Dao <i>et al.</i> , "Adhesion to fibronectin maintains regenerative capacity during <i>ex vivo</i> , culture and transduction of human hematopoietic stem and progenitor cells," <i>Blood</i> , 92:4612-4621, 1998.
<i>Sc</i>	C15	Dao <i>et al.</i> , "FLT3 ligand preserves the ability of human CD34+ progenitors to sustain long-term hematopoiesis in immune-deficient mice after <i>ex vivo</i> retroviral-mediated transduction," <i>Blood</i> , 89:446-456, 1997.
<i>Sc</i>	C16	DeZazzo <i>et al.</i> , "Involvement of long terminal repeat U3 sequences overlapping the transcription control region in human immunodeficiency virus type 1 mRNA 3' end formation," <i>Mol. Cell. Biol.</i> , 11:1624-1630, 1991.
<i>Sc</i>	C17	Donello <i>et al.</i> , "Woodchuck hepatitis virus contains a tripartite posttranscriptional regulatory element," <i>J. Virol.</i> , 72:5085-5092, 1998
<i>Sc</i>	C18	Dorrell <i>et al.</i> , "Expansion of human cord blood CD34(+)CD38(-) cells in <i>ex vivo</i> culture during retroviral transduction without a corresponding increase in SCID repopulating cell (SRC) frequency: dissociation of SRC phenotype and function," <i>Blood</i> , 95:102-110, 2000.
<i>Sc</i>	C19	Dull <i>et al.</i> , "A third-generation lentivirus vector with a conditional packaging system," <i>J. Virology</i> , 72:8463-8471, 1998.
<i>Sc</i>	C20	Feng and Holland, "HIV-1 Tat Trans-Activation Requires the Loop Sequence Within Tar," <i>Nature</i> , 334(6178):165-167, 1988.
<i>Sc</i>	C21	Gilmartin <i>et al.</i> , "Activation of HIV-1 pre-mRNA 3' processing <i>in vitro</i> requires both an upstream element and TAR," <i>Embo. J.</i> , 11:4419-4428, 1992.
<i>Sc</i>	C22	Gossen and Bujard, "Tight control of gene expression in mammalian cells by tetracycline-responsive promoters," <i>Proc. Natl. Acad. Sci.</i> , 89:5547-5551, 1992.
<i>Sc</i>	C23	Kafri <i>et al.</i> , "Sustained expression of genes delivered directly into liver and muscle by lentiviral vectors," <i>Nature Genetics</i> , 17:314-317, 1997.
<i>Sc</i>	C24	Kohn <i>et al.</i> , "Toward gene therapy for Gaucher disease," <i>Hum. Gene Ther.</i> , 2:101-105, 1991.
<i>Sc</i>	C25	Levenson <i>et al.</i> , "Internal ribosomal entry site-containing retroviral vectors with green fluorescent protein and drug resistance markers," <i>Human Gene Therapy</i> , 9:1233-1236, 1998.
<i>Sc</i>	C26	Lewis and Emerman, "Passage through mitosis is required for oncoretroviruses but not for the human immunodeficiency virus," <i>J. Virology</i> , 68:510-516, 1994.

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U.S. Patent Documents See Page 1	Foreign Patent Documents See Page 1	Other Art See Page 1	

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α	C27	Marthas <i>et al.</i> , "Viral determinants of simian immunodeficiency virus (SIV) virulence in Rhesus Macaques assessed by using attenuated and pathogenic molecular clones of SIVmac," <i>J. Virol.</i> , 67:6047-6055, 1993.
λ	C28	Mazurier <i>et al.</i> , "Rapid analysis and efficient selection of human transduced primitive hematopoietic cells using the humanized S65T green fluorescent protein," <i>Gene Ther.</i> , 5:556-562, 1998.
λ	C29	Miyoshi <i>et al.</i> , "Transduction of human CD34+ cells that mediate long-term engraftment of NOD/SCID mice by HIV vectors," <i>Science</i> , 283:682-686, 1999.
λ	C30	Mizushima and Nagata, "pEF-BOS, a powerful mammalian expression vector," <i>Nucleic Acids Res.</i> , 18:5322, 1990.
λ	C31	Naldini <i>et al.</i> , "Efficient transfer, integration, and sustained long-term expression of the transgene in adult rat brains injected with a lentiviral vector," <i>Proc. Natl. Acad. Sci. USA</i> , 93:11382-11388, 1996.
λ	C32	Naldini <i>et al.</i> , "In vivo gene delivery and stable transduction of nondividing cells by a lentiviral vector," <i>Science</i> , 272:263-267, 1996.
λ	C33	Naldini, "Lentiviruses as gene transfer agents for delivery to non-dividing cells," <i>Current Opinion in Biotechnology</i> , 9:457-463, 1998.
λ	C34	Ory <i>et al.</i> , "A stable human-derived packaging cell line for production of high titer retrovirus/vesicular stomatitis virus G pseudotypes," <i>Proc. Natl. Acad. Sci.</i> , 93:11400-11406, 1996.
λ	C35	Piacibello <i>et al.</i> , "Engraftment in nonobese diabetic severe combined immunodeficient mice of human CD34(+) cord blood cells after <i>ex vivo</i> expansion: evidence for the amplification and self-renewal of repopulating stem cells," <i>Blood</i> , 93:3736-3749, 1999.
λ	C36	Ramezani <i>et al.</i> , "Lentiviral vectors for enhanced gene expression in human hematopoietic cells," <i>Molecular Therapy</i> , 2:458-469, 2000.
λ	C37	Roe <i>et al.</i> , "Integration of murine leukemia virus DNA depends on mitosis," <i>Embo. J.</i> , 12:2099-2108, 1993.
λ	C38	Scharfmann <i>et al.</i> , "Long-term <i>in vivo</i> expression of retrovirus-mediated gene transfer in mouse fibroblast implants," <i>Proc. Natl. Acad. Sci. USA</i> , 88:4626-4630, 1991.

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See Page 1Foreign Patent Documents  
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## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
84	C39	Sutton <i>et al.</i> , "Human immunodeficiency virus type 1 vectors efficiently transduce human hematopoietic stem cells," <i>J. Virol.</i> , 72:5781-5788, 1998.
82	C40	Sutton <i>et al.</i> , "Transduction of human progenitor hematopoietic stem cells by human immunodeficiency virus type 1-based vectors is cell cycle dependent," <i>J. Virol.</i> , 73:3649-3660, 1999.
82	C41	Uchida <i>et al.</i> , "HIV, but not murine leukemia virus, vectors mediate high efficiency gene transfer into freshly isolated G0/G1 human hematopoietic stem cells," <i>Proc. Natl. Acad. Sci. USA</i> , 95:11939-11944, 1998.
84	C42	Ueda <i>et al.</i> , "Expansion of human NOD/SCID-repopulating cells by stem cell factor, Flk2/Flt3 ligand, thrombopoietin, IL-6, and soluble IL-6 receptor," <i>J. Clin. Invest.</i> , 105:1013-1021, 2000.
82	C43	Valsamakis <i>et al.</i> , "Elements upstream of the AAUAAA within the human immunodeficiency virus polyadenylation signal are required for efficient polyadenylation <i>in vitro</i> ," <i>Mol. Cell Biol.</i> , 12:3699-3705, 1992.
84	C44	Valsamakis <i>et al.</i> , "The human immunodeficiency virus type 1 polyadenylation signal: a 3' long terminal repeat element upstream of the AAUAAA necessary for efficient polyadenylation," <i>Proc. Natl. Acad. Sci. USA</i> , 88:2108-2112, 1991.
- 82	C45	Zufferey <i>et al.</i> , "Multiply attenuated lentiviral vector achieves efficient gene delivery <i>in vivo</i> ," <i>Nat. Biotechnol.</i> , 15:871-875, 1997.
- 82	C46	Zufferey <i>et al.</i> , "Self-inactivating lentivirus vector for safe and efficient <i>in vivo</i> gene delivery," <i>J. Virol.</i> , 72:9873-9880, 1998.
- 82	C47	Zufferey <i>et al.</i> , "Woodchuck hepatitis virus posttranscriptional regulatory element enhances expression of transgenes delivered by retroviral vectors," <i>J. Virol.</i> , 73:2886-2892, 1999.

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## U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
SE	A14	2001/0009772	7/26/01	Verma <i>et al.</i>	435	325	3/12/01
SE	A15	2002/0034393	3/21/02	Mitrophanous <i>et al.</i>	396	661	5/18/01
SE	A16	2002/0034502	3/21/02	Kingsman <i>et al.</i>	424	93.21	7/25/01
SE	A17	2002/0123471	9/5/02	Uberla	514	44	3/3/98
SE	A18	6,013,516	1/11/00	Verma <i>et al.</i>	435	325	10/6/95
SE	A19	6,096,538	8/1/00	Kingsman <i>et al.</i>	435	325	5/22/96
SE	A20	6,168,916 B1	1/2/01	Kingsman <i>et al.</i>	435	5	12/16/96
SE	A21	6,235,522 B1	5/22/01	Kingsman <i>et al.</i>	435	320.1	10/17/97
SE	A22	6,312,682 B1	11/6/01	Kingsman <i>et al.</i>	424	93.2	12/28/98
SE	A23	6,312,683 B1	11/6/01	Kingsman <i>et al.</i>	424	93.2	1/27/99
SE	A24	6,428,953 B1	8/6/02	Naldini <i>et al.</i>	435	5	6/26/00
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Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
SE	B1	WO 00/15819	3/23/00	PCT <i>WIPO</i>	/	/	
SE	B2	WO 00/55335	9/21/00	PCT <i>WIPO</i>	/	/	
SE	B3	WO 01/27304	4/19/01	PCT <i>WIPO</i>	/	/	
SE	B4	WO 01/34843	5/17/01	PCT <i>WIPO</i>	/	/	
SE	B5	WO 01/44481	6/21/01	PCT <i>WIPO</i>	/	/	
SE	B6	WO 01/92506	12/6/01	PCT <i>WIPO</i>	/	/	
SE	B7	WO 02/087341	11/7/02	PCT <i>WIPO</i>	/	/	
SE	B8	WO 99/04026	1/28/99	PCT <i>WIPO</i>	/	/	

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## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation
SH	C48	"A Phase I study of Ex vivo nerve growth factor gene therapy for Alzheimer's disease," sponsored by the Shiley Family Trust Institute for the Study of Aging, University of California, San Diego, Study ID Numbers IA0029, last reviewed June 2001.
SC	C49	"Ceregene exclusively licenses Neuturin gene from Washington University," Ceregene, Inc. Press Release, December 4, 2002.

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2	A26	4,682,195	7/21/87	Yilmaz	357	23.4	9/30/85
2	A27	4,683,202	7/28/87	Mullis	435	91	10/25/85
2	A28	5,466,468	11/14/95	Schneider <i>et al.</i>	424	450	10/28/94
2	A29	5,645,897	7/8/97	Andra	427	526	1/30/93
2	A30	5,705,629	1/6/98	Bhongle	536	25.34	10/20/95
2	A31	5,846,225	12/8/98	Rosengart <i>et al.</i>	604	115	2/19/97
2	A32	5,846,233	12/8/98	Lilley <i>et al.</i>	604	414	1/9/97
2	A33	5,925,565	7/20/99	Berlioz <i>et al.</i>	435	325	7/5/95
2	A34	5,928,906	7/27/99	Koster <i>et al.</i>	435	91.2	5/9/96
2	A35	5,935,819	8/10/99	Eichner <i>et al.</i>	435	69.4	1/2/97

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2	C50	Almendro <i>et al.</i> , "Cloning of the human platelet endothelial cell adhesion molecule-1 promoter and its tissue-specific expression. Structural and functional characterization," <i>J. Immunol.</i> , 157(12):5411-5421, 1996.
2	C51	Angel <i>et al.</i> , "12-O-tetradecanoyl-phorbol-13-acetate Induction of the Human Collagenase Gene is Mediated by an Inducible Enhancer Element Located in the 5' Flanking Region," <i>Mol. Cell. Biol.</i> , 7:2256-2266, 1987.
2	C52	Angel <i>et al.</i> , "Phorbol Ester-Inducible Genes Contain a Common cis Element Recognized by a TPA-Modulated Trans-acting Factor," <i>Cell</i> , 49:729-739, 1987.

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SC	C54	Atchison and Perry, "The Role of the $\kappa$ Enhancer and its Binding Factor NF- $\kappa$ B in the Developmental Regulation of $\kappa$ Gene Transcription," <i>Cell</i> , 48:121-128, 1987.
SC	C55	Banerji <i>et al.</i> , "A lymphocyte-specific cellular enhancer is located downstream of the joining region in immunoglobulin heavy-chain genes," <i>Cell</i> , 35:729-740, 1983.
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